DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

DRUGS FOR HUMAN USE

1980. Action to restrain interstate shipment of Dr. Paddock's Medicines. U. S. v. Edward E. Paddock. Permanent injunction granted. (Inj. No. 131.)

COMPLAINT FILED: On or about May 29, 1946, Western District of Missouri, against Edward E. Paddock, a physician, Kansas City, Mo. It was alleged in the complaint that the defendant had been engaged since 1932 in the business of distributing through the mails in interstate commerce various drugs known as *Dr. Paddock's Medicines*, consisting of yellow-coated tablets containing as active ingredients 3½ grains of extract of oxgall and 5 grains of sodium salicylate, blue-coated tablets containing as an active ingredient 5 grains of sodium succinate, and brown-coated laxative tablets containing 5 grains of cascara sagrada. It was also alleged that in order to inform purchasers of the uses of the drugs and to facilitate their sale, the defendant caused to be printed a booklet entitled "The Gall Bladder and Liver"; leaflets entitled "Appreciation" and "Heartfelt Gratitude"; a pamphlet entitled "Special Diet Directions"; form letters designated "Dear Friend," "Dear Reader," and "Dear Sufferer"; and combination order and report blanks requesting information as to age, weight, history, and physical condition of a person ordering the drugs, and bearing on the reverse side "Some Anatomical Explanations." It was further alleged that the literature and the drugs were distributed by the defendant by means of advertisements in newspapers; that in response to inquiries from the readers of the advertisements, the defendant would mail the literature and solicit orders for his drugs; and that by reason of these facts the literature constituted labeling accompanying the drugs.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the drugs were false and misleading in that they represented and suggested that the drugs, when used singly or in combination, together with the diets outlined in the pamphlet entitled "Special Diet Directions" would be a competent and palliative and symptomatic treatment for all gall bladder conditions; that the drugs would be efficacious in the cure, mitigation, treatment, and prevention of gallstones and an irritable and over-excited nervous system due to gall bladder trouble; that the drugs would insure that the user would obtain the greatest measure of relief possible; that the drugs would treat successfully partial obstruction of the bile flow; and that the drugs constituted a palliative and symptomatic treatment which would aid nature. The drugs, when used singly or in combination, with or without the diets outlined in the above pamphlet would not be a competent and palliative and symptomatic treatment for all gall bladder conditions; and the drugs would not be efficacious for the purposes represented.

Further misbranding, Section 502 (a), certain additional statements in the labeling were misleading since they created the impression that the drugs would cause no harm and could be used with safety to all; that the user could compare his symptoms before and after treatment to tell whether or not he was improving; that the user might safely temporize with gall bladder disorders and gallstones; that partial obstruction of the bile flow may be treated by the drugs; and that the drugs might be used safely and effectively without an accurate diagnosis. The drugs could cause harm and could not be used with safety by all, in that they contained a laxative and should not be used in the presence of symptoms of appendicitis; that the use of the drugs might cause dependence upon laxatives; that the drugs contained oxgall, and in cases of partial obstruction of the bile flow the drugs might increase the bile flow to such an extent that obstruction might become complete, causing pain, possible destruction of the liver, and even death; that the user could not compare symptoms before and after treatment and tell whether or not he was improving, for gallstones may be present and dangerous without causing painful symptoms; that the user might not safely temporize with gall bladder disorders or gallstones, for an emergency operation may be necessary in such conditions; and that the drugs could not safely and effectively be used without an accurate diagnosis, for such use might result in delaying proper treatment and might lead to unnecessary suffering and possible death.

PRAYER OF COMPLAINT: That a temporary restraining order issue followed by a temporary injunction, and that, after due proceedings, a permanent injunction

*See also Nos. 1953, 1955, 1957, 1961, 1968–1970, 1977–1979.

issue enjoining the defendant from distributing in interstate commerce the drugs he had on hand or would subsequently acquire.

DISPOSITION: The defendant having filed a motion to dismiss or, in the alternative, to strike certain averments of the complaint, the court, on June 21, 1946, handed down the following opinion overruling the motion:

REEVES, *District Judge:* "Pursuant to our arrangement, I have examined the authorities on the motion to dismiss, or in the alternative, to strike certain averments of the complaint, and have reached the following conclusion:

"The Food & Drug Act, designed to protect the health of the public, should be liberally construed to effectuate the purposes of the Congress. The literature and advertising matter covered by the motion was obviously designed by the defendant to serve as a labeling of his product. It had that unquestioned purpose. Under the decisions, such advertising matter may serve the two-fold purpose of advertising, and, at the same time, labeling. The provisions of the law could not be evaded by first placing the advertising and labeling matter in the hands of a prospective purchaser in advance of the purchase. It was the Congressional purpose to prevent fraud on the public. The usual and practical method of the producer was to send the labeling and advertising matter along with the product so that both would reach the purchaser at the same time. The identical result could be reached by sending the labeling matter in advance, or even subsequently. When both of them finally reached the consumer, there was the deception that the law seeks to prevent.

"If the law is as contended by the defendant, then the whole purpose of the law could be defeated by placing in the hands of the consumer, through separate channels, the labeling matter and the product. Such evasions could not be permitted.

"There is no conflict of jurisdiction between the Federal Trade Commission and the Court, as indicated in United States v. Research Laboratories, 126 F. 2d, 42, l. c. 45. Advertising and labeling circulars may be the same and yet perform the two offices of advertising and labeling. The courts have jurisdiction over the labeling function, whereas the Federal Trade Commission would have jurisdiction at the same time over the same circular because of its advertising function.

"The motion to dismiss, or, in the alternative, to strike, should be and will be overruled."

The case came on for trial before the court on June 26, 1946, and at its conclusion on June 27, the matter was taken under advisement by the court. After consideration of the briefs of the parties, the court, on September 28, 1946, handed down the following opinion, findings of fact, and conclusions of law:

OPINION

REEVES, *District Judge:* "This is an action under Section 332 (a) Title 21 U. S. C. A. to restrain the defendant from violations of Section 331 of said Title 21 U. S. C. A., in the following particular: The introduction of certain alleged misbranded drugs into interstate commerce. The issues were made up by an answer of the defendant which denied 'that he is transporting misbranded drugs in interstate commerce * * *.'

"The evidence on the part of the plaintiff tended to show that the defendant has been continuously from 1932 until the present time engaged in the business of distributing through the mails in interstate commerce drugs to be used in the treatment of gallstones, gall bladder diseases and diseased liver conditions, and that said drugs consisted of yellow coated tablets, blue coated tablets and brown coated tablets, and that such drugs were within the meaning of Section 321 (g) (2), Title 21 U. S. C. A. The evidence supported the averments of the complaint that certain exhibits proffered in the complaint and in evidence were regularly sent through the mails either with the drug thus distributed or prior or subsequent to its distribution and that the drugs and the literature came into the hands of patrons or purchasers of the drug and that such literature was intended by the defendant to be used in connection with the treatment advised by the defendant. As an illustration of the literature thus distributed through the mails to be associated with the drug when used, was one as follows:

[Exhibit H] HEARTFELT GRATITUDE from NORTH . . . SOUTH . . . EAST and WEST [Printed in large type]

and this was followed by a statement, blocked off in the advertisement, (also in large type) as follows:

Does Gall Bladder Irritation, Gall Distress and Sluggish Bile Threaten You[Then read MY 30 YEARS OF TREATING Earlier Symptoms to Avoid Development of GALLSTONE TROUBLES.

The two words GALLSTONE TROUBLES were printed in very large type.

"Four physicians who were specialists in the administration of internal medicines, and particularly familiar with gall bladder and liver complaints, testified that the drugs distributed by the defendant were ineffective for the purposes advertised and asserted by the defendant in his literature. And, moreover, that said drugs would be inefficacious in the prevention or the avoidance of the development of gallstone trouble. In fact, the testimony of these experienced physicians indicated that the drugs administered or delivered for administration by the defendant would act in a degree as an irritant and would be harmful in their use. Moreover, said witnesses further testified that diagnosis of gallbladder and liver trouble could not be satisfactorily made without a preliminary objective and subjective examination of the patient.

"On the part of the defendant two physicians were called who were not presently engaged in the practice of medicine and who had had little experience in the treatment of gall bladder and liver complaints. The witnesses for the defendant tended to support the contention of the defendant that his drugs were not misbranded and that they were useful and efficient as stated by him in his literature. The further contention is made by counsel for the defendant that the literature transmitted through the mails in interstate commerce was in no sense a labeling of the drugs but was purely advertising matter.

"1. The word 'labeling' has been defined in the Federal Food, Drug and Cosmetic Act, (New) Section 321, paragraph (m), Title 21 U. S. C. A. as follows:

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

As said by the Court of Appeals, 7th Circuit, in United States v. Lee, 131 F. 2d, 464, l. c. 466:

The word "accompany" is not defined in the Act, but we observe that among the meanings attributed to the word are "to go along with," "to go with or attend as a companion or associate," and "to occur in association with," * * * There can be no question that among the usual characteristics of labeling is that of informing a purchaser of the uses of an article to which the labeling relates, and that the basic character of the Federal Food, Drug, and Cosmetic Act is not directly concerned with the sale of the products therein described, or whether the literature is carried away by the purchaser. *It was enacted to protect the public health and to prevent fraud, and it ought to be given a liberal construction. Consequently, we are impelled to the conclusion that misbranding is cognizable under the Act if it occurs while the articles are being held for sale.*

Other discussions of the subject would indicate that it was the purpose of Congress to treat advertising matter as labeling, if used by the patron or purchaser, precisely in the same way as if the matter were accompanying the drug in the first instance.

"2. There is the further contention by the defendant that the testimony on behalf of the government did not point out that the particular formulas of the defendant were harmful. In the first place, in the trial of the case, it was assumed by all of the witnesses, both for the plaintiff and the defendant, on direct examinations and cross-examinations, that the precise formulas were in controversy and were under discussion by the expert witnesses, and, in the second place, the testimony on behalf of the government was that, without regard to precise formulas, the particular constituents of the formula or formulas were harmful and dangerous unless prescribed after a careful diagnosis of the patient's troubles.

"3. The defendant testified over the objection of counsel for the government that the years of his treatment by mail had not been attended by complaints from patients or patrons. Objection was properly made to such testimony and same should have been excluded. Moreover, certain medical books or texts were offered in evidence by the defendant over the objections of the plaintiff. It is the rule in this circuit, as in practically all of the states, that medical books are not competent as evidence.

"The overwhelming preponderance of the testimony was that the labeling and the literature treated as labels on the drugs introduced by the defendant into interstate commerce constituted a misbranding of drugs and that the government was entitled to have the defendant restrained from the further introduction of said drugs in interstate commerce.

"The attention of the court has been called to the fact that since the case was tried and submitted the defendant has deceased. The government, there-

fore, could proceed no further in the case. Since the government was entitled, at the time the case was tried, to a judgment or decree as prayed, and, in view of the death of the defendant, a decree will be entered nunc pro tunc as of the date the case was submitted.

FINDINGS OF FACT

"1. All of the literature used by the defendant and offered in evidence, whether used over the container of the drug or in the packages, actually physically accompanying the drug, or whether sent before, or subsequently, served the function of labeling and should be treated as such.

"2. Such literature and drugs were introduced and were being introduced by the defendant in interstate commerce through the mails as alleged in the complaint.

"3. Said literature was intended by the defendant as a labeling of his drug and actually served that purpose as well as for advertising matter.

"4. Said literature as labeling matter misrepresented the efficaciousness of said drug or drugs and operated as a fraud upon the public.

CONCLUSIONS OF LAW

"1. The defendant having misbranded his drugs by labels attached thereto or accompanying same, and such misbranding having been done in interstate commerce, the defendant should be enjoined from further violations of Section 331, Title 21 U. S. C. A."

On or about October 14, 1946, a decree was entered permanently enjoining the defendant, his agents, and all persons at that time or thereafter, acting by, through, or under the defendant, from distributing in interstate commerce or exporting in foreign commerce a large supply of the tablets which he had on hand at his place of business in Kansas City, Mo., or at any other point, or any other quantity of drugs subsequently acquired, which were misbranded; and it was further ordered that the decree take effect as of September 27, 1946.

1981. Action to enjoin and restrain the interstate shipment of Mag-Net-O-Balm. U. S. v. Samuel Cohen (S. C. Sales Co.). Injunction granted. (Inj. No. 136.)

COMPLAINT FILED: On March 15, 1946, District of Maryland, against Samuel Cohen, an individual, and Samuel Cohen, trading as S. C. Sales Co. The complaint charged that prior to and since July 1, 1945, the defendant had been shipping in interstate commerce consignments of *Mag-Net-O-Balm*, a drug, which was misbranded in various respects.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements on the tubes and cartons and in a circular accompanying a shipment made on or about July 11, 1945, were false and misleading since the statements in the labeling represented that the article would be efficacious in the treatment of reducible rupture, rheumatic pains, chest colds, head colds, symptomatic rheumatic pains, muscular lumbago, stiff neck, sprains, and sciatica. Other shipments of the product made prior to that time were misbranded because of similar false and misleading curative and therapeutic claims.

PRAYER OF COMPLAINT: That the defendant be restrained and enjoined, during the pendency of the action and permanently, from shipping in interstate commerce misbranded drugs.

DISPOSITION: May 29, 1946. The defendant having failed to file an answer or any other pleading, a permanent injunction was granted against the defendant individually, and trading as the S. C. Sales Co., from shipping in interstate commerce the drug, *Mag-Net-O-Balm*.

1982. Misbranding of Allen's Nijara Capsules. U. S. v. Allen Products Co., Inc., and Marion Allen. Pleas of guilty. Fine, $75. (F. D. C. No. 10539. Sample Nos. 37131–F, 37143–F, 37149–F.)

INFORMATION FILED: March 24, 1945, District of Columbia, against the Allen Products Co., Inc., Washington, D. C., and Marion Allen, president of the corporation.

ALLEGED SHIPMENT: On or about February 24 and March 23, 1943, within the District of Columbia.